UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

In re REPROS THERAPEUTICS, INC. SECURITIES LITIGATION

Civil Action No. 4:09-cv-02530

DEFENDANTS' MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

This is a securities fraud case against a biopharmaceutical company, Repros Therapeutics, Inc. ("Repros"), and three of its officers. During pivotal clinical trials of its lead drug, Proellex, Repros discovered a safety problem related to elevated liver enzymes. Repros immediately disclosed the problem in a July 1, 2009 press release, issued further press releases with additional detail about the affected patients, and continued clinical trials at lower dose levels. After review of additional data and input from a panel of experts, Repros cancelled all Proellex trials on August 3, 2009. Plaintiffs, who purchased Repros stock after the liver enzymes issue was disclosed but prior to the cancellation of all clinical trials, allege that Repros knew from the start that the trials would be cancelled but did not disclose this information in order to raise capital. Plaintiffs' sole basis for their claim is that Defendants must have known of the further negative results before they were disclosed. Plaintiffs plead no facts in support of this contention, and their bare allegations constitute the type of "fraud by hindsight" pleading that courts routinely reject.

Under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), to survive dismissal, Plaintiffs' Complaint must specifically identify a false or misleading statement or omission by Defendants, explain why it is false or misleading, and plead with particularity facts giving rise to a strong inference that Defendants acted with scienter. Plaintiffs' Complaint comes nowhere close to meeting this standard. Plaintiffs have pleaded no facts showing that any Defendant knew anything about the liver enzymes issue contrary to what was disclosed in the press releases, nor have they pleaded any facts indicating that any Defendant knew about the elevated liver enzymes at any time before the press releases disclosed the issue. Although Plaintiffs theorize that Defendants were motivated to hide the issue because Repros needed to raise capital, Plaintiffs have not alleged that Repros even *tried* to raise capital, let alone

succeeded. And, perhaps most importantly, Plaintiffs have offered no explanation, because there is none, for why Repros would have disclosed the problem at all—let alone the specific number of patients affected and how they were affected—if Defendants truly intended to hide the problem from the public.

As courts have repeatedly recognized, investing in companies dependent on a single, development-stage drug involves the substantial risk that the drug will fail, whether at the clinical trial stage or thereafter. Indeed, Defendants regularly and clearly notified all investors in numerous public filings of the risks surrounding an investment in a drug in the middle of clinical testing. The fact that those warnings ultimately became reality does not constitute a claim for securities fraud. To make out such a claim, Plaintiffs must provide some evidence that a statement was false when made and that the speakers knew it to be false. The total absence of such facts dooms Plaintiffs here. Accordingly, Plaintiffs' Complaint should be dismissed under Rules 9(b) and 12(b) of the Federal Rules of Civil Procedure and the PSLRA.

II. BACKGROUND FACTS

Defendant Repros is a development-stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs. Defendants Paul Lammers, Louis Ploth, and Joseph Podolski (the "Individual Defendants") were officers of Repros during the Class Period. Plaintiffs, purchasers of Repros stock from July 1, 2009 through August 2, 2009 (the "Class Period"), generally allege that Defendants made false and misleading statements regarding the safety of Repros's lead drug, Proellex, in three July 2009 press releases.

Proellex was developed to treat three indications: (1) anemia associated with uterine fibroids; (2) chronic treatment of symptoms associated with uterine fibroids; and (3) chronic treatment of symptoms associated with endometriosis. Before it could be marketed, Proellex had to meet regulatory approval requirements, including completion of Phase 1,

Phase 2, and Phase 3 clinical trials, as well as any other requirements imposed by the Federal Drug Administration ("FDA"), such as completion of additional clinical tests.[1] Ex. 4 (2008 10-K, at 3).[2]

By January 2009, Repros had completed animal studies, Phase 1 trials, and three Phase 2 trials on Proellex. Ex. 5 (Mar. 31, 2009 10-Q, at 15-16). As the company repeatedly disclosed, however, those trials did not represent the end of Repros's testing of the drug. To the contrary, a variety of clinical trials, including Phase 3 trials and Open Label Safety Trials (in which patients from completed Phase 2 trials were studied for several additional months) were in progress and continued into the Class Period. *Id.* At the same time, Repros continued some Phase 1 trials and animal safety studies. *Id.* The trials tested three dosage levels of Proellex: 50 mg, 25 mg and 12.5 mg. Ex. 4 at 3. On May 16, 2009, Repros estimated that it would complete its Proellex trials and submit New Drug Applications in 2010 and 2011, but it expressly cautioned investors that the company "currently do[es] not have reliable estimates regarding the timing of our Proellex clinical trials." *Id.* at 29.

Repros continued to advise the investing public about the uncertainty of its clinical trials, as well as the drug itself, throughout the first half of 2009. For example, in the 2008 Form 10-K issued three months before the Class Period began, Repros emphasized that despite the completion of Phase 2 trials, the company had not completed any pivotal or long-term

---

[1] "Phase I studies generally involve twenty to eighty subjects, and are designed to determine how the drug works in humans and the side effects associated with increasing doses. Phase II studies usually involve no more than several hundred subjects, and are designed to evaluate the effectiveness of the drug, as well as common short-term side effects and risks. Phase III studies are large-scale trials, usually involving several hundred to several thousand subjects, and are intended to gather the information necessary to provide an adequate basis for labeling the drug. . . After Phase III, the FDA considers the results of all of the clinical trials in determining whether to approve a drug for market." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 39 (1st Cir. 2008) (citations omitted).

[2] Each document in the attached appendix either has been incorporated into the Complaint or may be judicially noticed and, therefore, may properly be considered by the Court in deciding this motion to dismiss. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000); *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1018 (5th Cir. 1996).

trials on Proellex, leaving the ultimate viability and safety of the drug in question:

> All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy. *We caution that the results discussed herein are based on data from non-pivotal trials and that our pivotal Phase 3 and long-term Open Label Safety Study data may not agree with these results* which will be based upon a significantly larger and more diverse patient population treated for longer periods of time.

Id. at 3 (emphasis added). Repros further cautioned that,

> *Positive data from preclinical studies or early clinical trials should not be relied upon as evidence that those studies or trials will produce positive results, or that later or larger-scale clinical trials will succeed*. . . . The limited data we have obtained may not predict results from studies in larger numbers of patients drawn from more diverse populations, and may not predict the ability of Proellex to treat [various indications]. . . . We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale which we have only recently initiated for Proellex in our registration Pivotal Phase 3 trials. *There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials.*

Id. at 14 (emphasis added). As these and many similar disclosures made clear,[3] Repros never guaranteed the safety or marketability of Proellex. To the contrary, it repeatedly warned investors that "long-term safety and efficacy have not yet been demonstrated in clinical trials" for Proellex and that many drugs failed to make it though clinical trials. *Id.* at 17.

On July 1, 2009—the first day of the Class Period—Repros issued a press release providing an update on its Proellex clinical program. Ex. 6. Repros noted that it had decided to

[3] *E.g.*, Ex. 12 (June 5, 2009 Press Release) (warning that "final data may not be consistent with interim data"); May 11, 2009 Press Release (same); Apr. 17, 2009 Press Release (same); Mar. 20, 2009 Press Release (same); Mar. 16, 2009 Press Release (same); Mar. 12, 2009 Press Release (same); Feb. 23, 2009 Press Release (same); Feb. 3, 2009 Press Release (same); Jan. 27, 2009 Press Release (same); Jan. 12, 2009 Press Release (same); Dec. 22, 2008 Press Release (same); Nov. 10, 2008 Press Release (same); Aug. 21, 2008 Press Release (same); Aug. 18, 2008 Press Release (same); July 16, 2008 Press Release (same); July 14, 2008 Press Release (same); July 11, 2008 Press Release (same); May 29, 2008 Press Release (same); May 9, 2008 Press Release (same); Mar. 31, 2008 Press Release (same); Mar. 17, 2008 Press Release (same); *see also* Ex. 5 at 15 (cautioning that "results discussed herein are based on data from non-pivotal trials and that our pivotal Phase 3 and long-term Open Label Safety Study data may not agree with these results").

discontinue the 50 mg dose in response to "an observed dose-dependent increase in liver enzymes in a low percentage of women." *Id.* Repros stated that it did not believe this situation would affect the efficacy of the drug because the 50 mg dose had not been shown to work better than the 25 mg dose. *Id.* However, Repros in no way indicated that any dose of Proellex had been demonstrated as safe. Repros did state that "[f]rom completed studies as well as from the ongoing large open label trial, it has been determined that the drug is well tolerated with few women discontinuing treatment due to adverse events," but Repros cautioned investors that the clinical studies to date included a limited patient population and that "final data may not be consistent with interim data." *Id.* Coupled with Repros's prior disclosures, this disclosure can only be read as further interim information that reflected current knowledge but offered no commitment as to final testing outcomes.

Six days later, on July 7, Repros issued another press release that disclosed data about the patients treated with Proellex through June 2009. Ex. 7. Repros reported that of the 470 women treated with Proellex through June 2009, ten had discontinued treatment due to an increase in liver enzymes. *Id.* Nine of the ten had been on the higher 50 mg dose, while the tenth patient, who had been on the 25 mg dose, had a possible pre-existing condition. *Id.* Repros also repeated the company's belief that the lower doses of Proellex "will offer comparable efficacy benefits while providing an improved safety profile." *Id.* And, Repros reiterated that the clinical studies to date involved only a limited patient population and that the final data might not be consistent with the interim data then available. *Id.*

That same day, Repros entered into an amendment to its licensing agreement with the National Institute of Health ("NIH") relating to Proellex (the "NIH Amendment"),

which Repros publicly announced one day later, on July 8.[4] Ex. 8. The NIH Amendment "revised the dates by which certain development and commercialization benchmarks must be met," extending Repros's deadline to submit a New Drug Application on Proellex for two years, to June 30, 2011. *Id.* The NIH Amendment also required Repros to obtain $6 million in financing by September 30, 2009. *Id.*

The need to raise capital was not a new issue for Repros. The company had experienced significant operating losses in each fiscal year since its inception. Ex. 1 (2007 10-K, at 14). Moreover, since at least March 17, 2008, and continuing through the Class Period, Repros had reported that its ability to continue as a going concern depended on the success of the Proellex trials.[5] Plaintiffs do not allege that Repros raised any capital during the Class Period.

On July 23, 2009, Repros issued yet another press release on the Proellex clinical trial data. Ex. 9. The July 23 press release provided an update on the medical progress of the ten patients identified in the July 7 press release and stated that Repros intended to obtain guidance from the FDA on the clinical and regulatory pathways for the Proellex trials. *Id.* Repros again warned investors of "risks and uncertainties, including . . . limited patient populations of clinical studies to date and the possibility that final data may not be consistent with interim data." *Id.*

On August 3, 2009—the day after the Class Period ended—Repros announced that it was voluntarily suspending dosing of all patients in its Proellex clinical trials. Ex. 10.

---

[4] Repros has licensed rights to Proellex from the NIH since 1999. Ex. 4 at 7-8.

[5] *See* Ex. 5 at 18 ("We believe that we will secure sufficient capital to continue our ongoing and planned clinical programs assuming that the results of our current ongoing clinical trials with Proellex are favorable. If the results of these trials are unfavorable, there can be no assurance that the Company will be successful in obtaining additional capital in amounts sufficient to continue to fund its operations, which outcome would have a material adverse effect on the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months."); *see also* Ex. 4 at 30 ("We believe we can secure additional cash resources . . . assuming that the results of our ongoing Proellex clinical trials are favorable."); Ex. 3 (June 30, 2008 Form 10-Q, at 23) (same); Ex. 2 (Mar. 31, 2008 Form 10-Q, at 21) (same); Ex. 1 at 28 (same). The press releases about which Plaintiffs complain likewise note the risk that Repros may fail "to raise additional capital in a timely manner and on acceptable terms." Exs. 6-7, 9-11.

Repros reported that its decision was based upon unaudited data that had been acquired from clinical trial databases and "recent input from a consulting panel of liver experts." *Id.* Three days later, on August 6, the FDA placed a clinical hold on Proellex. Ex. 11.

In their Complaint, Plaintiffs allege that because Repros had completed Phase 2 trials by January 2009, Defendants must have known at some unspecified time before the start of the Class Period that the liver enzymes issue was so severe as to render Proellex unsafe and unmarketable at any dosing level. Specifically, Plaintiffs assert that "Repros investors believed that any major toxicity problems would have been revealed" at the conclusion of the Proellex Phase 2 trials in January 2009 and ask the Court to infer that Defendants must have withheld negative information from investors. Plaintiffs also attribute two allegedly false statements to Defendants: (1) the statement that Proellex was "well tolerated" in the July 1 press release; and (2) the statement "that Repros had a reasonable basis to believe that 'the 25 mg and 12.5 mg doses [of Proellex] will offer comparable efficacy benefits while providing an improved safety profile'" in the July 7 press release. (Compl. ¶¶ 40, 45.) Plaintiffs further allege that the July 1, 7, and 23 press releases are misleading because they "failed to reveal that the issues regarding elevated liver enzymes were so severe that they could lead to the cancellation of all of the Proellex trials" and "failed to reveal that Defendants issued news on Proellex's safety that had no reasonable basis in fact." (*Id.* ¶¶ 40, 45, 48.) According to Plaintiffs, Defendants withheld negative information about Proellex during the Class Period because Repros was trying to raise capital to meet the September 30 financing deadline in the NIH Amendment.

III. ARGUMENT

To state a securities fraud claim under Section 10(b) and Rule 10b-5, Plaintiffs must plead with particularity the following elements: (1) a material misrepresentation or

omission; (2) a defendant with scienter concerning the fraud; (3) reliance; (4) damages; and (5) loss causation. *Ind. Elec. Workers' Pension Trust Fund IBEW v. Shaw Group., Inc.*, 537 F.3d 527, 532 (5th Cir. 2008). In deciding a Rule 12(b)(6) motion to dismiss in a case brought under Section 10(b) and Rule 10b-5, a court must accept all factual allegations in the complaint as true. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-24 (2007). However, to survive a motion to dismiss, the complaint must satisfy the heightened pleading standards of Rule 9(b) and the PSLRA. *Id.* at 319-23. The PSLRA enhanced the "particularity" requirement for pleading securities fraud under Rule 9(b) in two ways. *Id.* Not only must plaintiffs specify each allegedly false or misleading statement or omission, but they also must specify the reasons why it is false or misleading. Moreover, for each properly alleged misrepresentation or omission, the plaintiffs must state with particularity facts giving rise to a strong inference that the defendants acted with scienter. 15 U.S.C. § 78u-4(b)(1)-(2) (2006). The PSLRA thus requires a plaintiff to "lay out the who, what, when, and where in the pleadings *before* access to the discovery process is granted, to prevent abusive, frivolous strike suits." *Goldstein v. MCI WorldCom*, 340 F.3d 238, 257 (5th Cir. 2003).

In performing this analysis, this Court must consider plausible nonculpable explanations for Defendants' conduct in order to determine whether Plaintiffs have adequately pleaded scienter. *Tellabs*, 551 U.S. at 322-24. To do so, the Court must consider the Complaint in its entirety, along with other documents that courts routinely examine in deciding motions to dismiss securities fraud cases, such as (1) documents incorporated into the Complaint by reference and (2) other judicially noticeable documents such as SEC filings. *Id.*; *Collins*, 224 F.3d at 498-99; *Lovelace*, 78 F.3d at 1017-18. The Complaint must raise an inference of scienter "at least as compelling" as any opposing inference. *Tellabs*, 551 U.S. at 324.

A. Plaintiffs have failed to plead falsity with sufficient particularity.

Plaintiffs allege that Repros issued two false statements of fact. The PSLRA requires that a plaintiff specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading. *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 361-62 (5th Cir. 2004). Although Plaintiffs allege that Repros's statement that Proellex was "well tolerated" and its representation that it believed that the 25 mg and 12.5 mg dose would offer a comparable efficacy and improved safety profile are false (Compl. ¶¶ 40, 45), Plaintiffs have not identified any factual basis to support a claim that these statements were false when made. For example, Plaintiffs do not allege that the statement that Proellex was "well tolerated" could not truthfully coexist with the discovery of liver enzyme issues in a low percentage of patients. But even if Plaintiffs had done so, the very same press release in which Repros stated that the drug, to date, had been well tolerated also disclosed the liver enzymes issue. Ex. 6. In light of that disclosure, there simply is no pleaded basis for claiming the statement that Proellex was "well tolerated" could be viewed as false. Likewise, Plaintiffs do not offer any reason why the extensive testing and data described in the July 7 press release provided insufficient support for the company's belief in the viability of the lower doses of Proellex.

A conclusory allegation that a statement is false is not sufficient to plead falsity with particularity as required under the PSLRA and Rule 9(b). *E.g., Panda Energy Int'l, Inc. v. Calpine Corp.*, No. 3:03-CV-2692-B, 2008 WL 3523896, at *2-3 (N.D. Tex. Aug. 13, 2008) (attached as Ex. 13). Because conclusory allegations of falsity are all that Plaintiffs have offered with respect to Defendants' alleged misrepresentations of fact, Plaintiffs have failed to meet their burden.

Plaintiffs also allege that Repros's July 1, 7, and 23 press releases are misleading because Repros failed to reveal that the liver enzymes issues "were so severe that they could lead

to the cancellation of all of the Proellex trials" and "failed to reveal that Defendants issued news on Proellex's safety that had no reasonable basis in fact" in order to increase Repros's chances of raising capital. (Compl. ¶¶ 40, 45, 48.) But, Plaintiffs' Complaint wholly fails to identify what statements in the three press releases were misleading due to the alleged omissions, much less how those statements were misleading. *See Southland*, 365 F.3d at 361-62. Plaintiffs fail to plead any specific facts known to Defendants at the time of the July 1, July 7, and July 23 press releases that would have made those press releases any clearer or more correct. Indeed, Defendants repeatedly had disclosed that there were significant risks related to the safety of Proellex and offered no assurances that safety ultimately would be demonstrated. Plaintiffs, therefore, have failed to plead the alleged misrepresentations by omission with the requisite particularity.

B. Plaintiffs' allegations fail to establish the required strong inference of scienter.

Under the PSLRA's pleading requirements for scienter, Plaintiffs must state with particularity facts giving rise to a strong inference that Defendants acted with the required state of mind for each alleged misrepresentation. 15 U.S.C. § 78u-4(b)(2); *Shaw*, 537 F.3d at 533. The required state of mind for a Section 10(b) fraud claim is an "intent to deceive, manipulate, or defraud, or severe recklessness." *Shaw*, 537 F.3d at 533. Severe recklessness is "limited to those highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and that present a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it." *Rozenzweig v. Azurix Corp.*, 332 F.3d 854, 866 (5th Cir. 2003) (citations omitted).

Critically, a plaintiff must allege facts to show that each defendant had the

requisite state of mind *at the time the particular representation was made*. *See Lormand v. US Unwired, Inc*, 565 F.3d 228, 254 (5th Cir. 2009). Courts will not infer "that the fact that something turned out badly must mean [that the] defendant knew earlier that it would turn out badly." *Id.* (internal quotation marks and citation omitted). Furthermore, a plaintiff cannot rely upon "the collective knowledge of all the corporation's officers and employees acquired in the course of their employment" and instead must plead facts about the state of mind of each defendant. *See Southland*, 365 F.3d at 365-66.

In reviewing scienter allegations, the question for the court is "whether all of the facts alleged, taken collectively, give rise to a strong plausible inference of scienter." *Lormand*, 565 F.3d at 251. "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Id.* at 251-52. A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. 324 (emphasis added).

In this case, Plaintiffs' Complaint suggests that Defendants acted with the requisite scienter because Repros had completed three Phase 2 clinical trials before the Class Period began and because Repros needed to raise capital during the Class Period. Neither theory supports an inference of scienter, much less a "strong plausible" one.

1. Plaintiffs' allegations regarding the Proellex Phase 2 clinical trials are insufficient to support a strong inference of scienter.

Plaintiffs' scienter allegations depend primarily on the theory that because Repros had completed Phase 2 trials by January 2009, Defendants must have known when the Class Period began that there was a liver enzymes issue with Proellex at all doses and that the liver enzymes issue was so severe that it would lead to the cancellation of all Proellex clinical trials.

But Plaintiffs' Complaint contains no facts showing that Repros knew anything about the liver enzymes issue with Proellex any earlier than reported or that any Defendant possessed knowledge contrary to Repros's public disclosures when those disclosures were made. For example, no facts are pleaded indicating that any Defendant believed during the Class Period that the liver enzymes issue affecting a small percentage of patients taking the 50 mg dose also jeopardized the 25 mg and 12.5 mg doses. Nor are there any facts pleaded indicating that any Defendant believed during the Class Period that the liver enzymes issue would require cancellation of all Proellex clinical trials. More importantly, Plaintiffs do not explain why, if Defendants were intent on hiding the liver enzymes issue, Repros disclosed the issue with the 50 mg dose at all, much less in the detail that it did.

Instead, Plaintiffs conclusorily allege that by the end of the Proellex Phase 2 trials in January of 2009, "Repros should have had a complete set of data regarding any adverse health effects, including elevated liver enzymes," in its "electronic data capture system" ("EDCS"). (Compl. ¶¶ 28, 30, 36-37.) Plaintiffs' theory rests on three false premises: (1) that any and all "major toxicity problems" with Proellex necessarily would have been revealed by the time Repros completed its Phase 2 trials (Compl. ¶ 29); (2) that "all relevant safety data had seemingly been analyzed" by January 2009, when Repros completed its Phase 2 trials (Compl. ¶ 56(e)); and (3) that the EDCS contained something more or different than what Repros disclosed about the liver enzymes issue during the Class Period (Compl. ¶¶ 28, 56).

First, there is no support for Plaintiffs' assumption that any safety issues with a drug necessarily will surface in Phase 2 clinical trials. Clinical trials are inherently risky and uncertain endeavors. As the First Circuit noted, "the investing public is well aware that drug trials are exactly that: trials to determine the safety and efficacy of experimental drugs. And so

trading in the shares of companies whose financial fortunes may turn on the outcome of such experimental drug trials inherently carries more risk than some other investments." *Biogen*, 537 F.3d at 48 (affirming dismissal of securities fraud claim against drug company and its executives where plaintiffs failed to plead strong inference of scienter). Further, it is beyond dispute that safety concerns may appear for the first time in a Phase 3 clinical trial, *see, e.g.*, *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 626-27 (S.D.N.Y. 2008) (explaining that Pfizer stopped clinical trials because of safety concerns raised during a Phase 3 trial), or even after all trials have been completed and the FDA has approved a drug for marketing. *See, e.g.*, *In re Bayer AG Sec. Litig.*, No. 03 Civ. 1546 WHP, 2004 WL 2190357, at *2-5 (S.D.N.Y. Sept. 30, 2004) (attached as Ex. 14) (discussing FDA-approved drug that was pulled from the market after post-marketing adverse event reports revealed serious safety concerns). Because a safety issue can arise at any time, even after a Phase 2 trial is complete, the inference that Defendants did not know the severity and repercussions of the liver enzymes issue at the completion of the Phase 2 trials is more compelling than the inference that Plaintiffs ask the Court to draw.

Second, Plaintiffs' assertion that Repros had "seemingly" analyzed all relevant safety data by the start of the Class Period is belied by the very SEC filings quoted by Plaintiffs. Repros repeatedly stated that it had completed only "non-pivotal" clinical trials and possessed only interim data, and Repros publicly reported that the final data could be different. In fact, the 2008 Form 10-K relied upon by Plaintiffs expressly warns that Repros had not completed pivotal clinical trials and that the data available was not final. Ex. 4 at 3, 14. In addition, the very press releases that Plaintiffs claim are misleading each make clear that clinical trials and data analysis were ongoing and caution that "final data may not be consistent with interim data." Ex. 6 (July 1 press release) ("Repros plans to initiate these studies . . . during the fourth quarter of [2009] and

the first quarter 2010); Ex. 7 (July 7 press release) (referencing "ongoing Phase III clinical trials"); Ex. 9 (July 23 press release) ("[S]ubjects in all ongoing trials are being monitored frequently"; Repros "intends to obtain guidance from the FDA in the coming months on the clinical . . . pathways forward for the Proellex clinical programs."). Thus, even after the completion of the Phase 2 trials described in the Form 10-K, Repros investors knew that Repros's analysis of safety data was not complete and that Proellex was still being studied and tested. Plaintiffs simply ignore these repeated statements and assert—without any basis at all—that Repros must have had all the data in its possession and completed analysis of that data.

This claim lacks any foundation. A far more plausible inference—because it is supported by repeated statements in SEC filings—is that the company was analyzing data as it became available and disclosing the results as that analysis was completed. Indeed, the fact that Repros disclosed the liver enzymes issue when discovered as to the 50 mg dose—a disclosure that only could have had negative effects on the Company—is fully consistent with the inference that Repros disclosed information about its clinical data as soon as it was available.

Third, Plaintiffs do not plead what, if anything, the EDCS would have shown about the liver enzymes issue during the Class Period beyond what Repros actually disclosed. The Complaint is devoid of any facts about what specific information was contained in the EDCS, how that information would inform Defendants of liver enzymes problems with Proellex and the extent of those problems, how any such problems were inconsistent with Repros's public disclosures, who at Repros reviewed and analyzed the data contained in the EDCS, or with whom any such persons shared any such analysis. In the absence of any facts about the data allegedly contained in the EDCS at the time of Repros's alleged failure to disclose the liver enzymes issue, the mere existence of the EDCS is insufficient to raise an inference of scienter.

See, e.g., *Shaw*, 537 F.3d at 540 (holding that allegations that "defendants knew or should have known that Shaw was prematurely recognizing revenue" because of monthly reports to management did not raise inference of scienter because complaint did not "allege that the reports or the meetings included information at odds with Shaw's public statements"); *Southland*, 365 F.3d at 370 (rejecting as insufficient basis for scienter allegations that defendants had "access to internal" data because plaintiffs did not allege any detail regarding content of internal data).

Furthermore, Plaintiffs have not pleaded facts demonstrating that any Individual Defendant was aware of any information apart from that reflected in Repros's disclosures. For example, Plaintiffs do not plead any facts to demonstrate that any Individual Defendant used Repros's EDCS to review any data, that any Individual Defendant had the background or training necessary to interpret the data in the EDCS, or that any Individual Defendant received any specific information from the EDCS or elsewhere about the liver enzymes issue contrary to that contained in Repros's disclosures. Instead, Plaintiffs suggest that the Individual Defendants must have known the full extent of the liver enzymes issue with Proellex based on their positions with the company. (*See* Compl. ¶¶ 14, 56(c).) This position ignores the repeated holding by the Fifth Circuit that an officer's position with a company does not suffice to create an inference of scienter. *See, e.g., Shaw*, 537 F.3d at 535; *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 211-12 (5th Cir.), *cert. denied*, 130 S. Ct. 199 (2009); *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 432 (5th Cir. 2002).

Any inference that Defendants were somehow withholding information about the liver enzymes issue is further contradicted by the fact that Defendants repeatedly disclosed adverse information about Proellex. When clinically significant increases in liver enzymes were discovered, Repros took the appropriate steps of conferring with a panel of liver experts and

suspending its clinical trials and made the appropriate disclosures on a timely basis. Because Defendants regularly disclosed negative information about Proellex—including information about elevated liver enzymes that could have only a negative effect on the Company's value—as it became available, the most compelling inference is that Defendants truthfully expressed their continuing, informed belief that, based on the available information, the drug would continue to move forward at the lower dose levels. Thus, the inference that Plaintiffs ask the Court to make—that Defendants acted with scienter and withheld information—is not "at least as compelling as any opposing inference." *Tellabs*, 551 U.S. at 324; *see also Johnson v. Pozen Inc.*, No. 1:07CV599, 2009 WL 426235, at **21-22 (M.D.N.C. Feb. 19, 2009) (attached as Ex. 15) (holding that plaintiffs' allegations that pharmaceutical company did not sufficiently explain toxicity results because company was trying to mislead investors about likelihood that drug would be approved by FDA were insufficient to raise a strong inference of scienter).

At the end of the day, Plaintiffs are left with nothing more than an allegation that because Repros ultimately stopped all Proellex clinical trials due to the liver enzymes issue, Defendants must have known earlier that the liver enzymes issue was severe enough to jeopardize the Proellex clinical trial program. Such an allegation amounts to impermissible fraud by hindsight. *See Lormand*, 565 F.3d at 254 (describing the classic "fraud by hindsight" scenario as one in which "a plaintiff alleges that the fact that something turned out badly must mean defendant knew earlier that it would turn out badly" (quoting *Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 91 (1st Cir. 2008))).

In cases like this one, where the ultimate failure of a clinical trial is offered as proof that defendants knew during the class period of that outcome, courts have specifically rejected attempts to infer earlier knowledge based only on the situation that later came to pass.

For example, in *Biogen*, the plaintiffs alleged that Biogen and its senior executives knew of patients who had suffered infections from use of Biogen's drug for some time prior to pulling the drug from the market. 537 F.3d at 48. The First Circuit, relying on numerous "paradigmatic" securities fraud cases "against drug development companies where a promising drug or medical device is approved by the FDA and then later proves to have health risks which affect the market for the drug," affirmed dismissal of the case because plaintiffs failed to allege facts both as to when defendants had information about the infections and that the information suggested a causal relationship between the infections and the drug. *Id.* at 47-49. Absent such a pleading, the plaintiffs could not state a claim for securities fraud. *Id.* As noted by the *Biogen* court, "defendants cannot have committed fraud if they did not know *at the time* that the failure to provide additional information was misleading." *Id.* at 48; *see also Pfizer*, 538 F. Supp. 2d at 634 (dismissing securities fraud case and noting that the fact that a drug ultimately fails due to unmanageable side effects is not evidence sufficient to establish liability under Rule 10b-5 absent evidence that defendants knew that side effects were unmanageable during class period).[6] Plaintiffs here likewise have failed to plead such facts.

2. Repros's financial status does not support the required strong inference of fraud.

Alternatively, Plaintiffs assert that Defendants engaged in "a campaign to conceal or minimize negative news about Proellex" in order to maximize the chance of obtaining the financing required by the NIH Amendment. (*See* Compl. ¶¶ 33, 37, 40, 45, 48, 56(f).) It is well settled, however, that allegations of scienter may not be based solely on motives universal to corporate executives, such as the motivation to raise capital. *Shaw*, 537 F.3d at 544; *see GSC*

[6] In contrast, in the complaint at issue in *Lormand*, the plaintiffs described contemporaneous internal emails and memoranda demonstrating that "the defendants privately knew, at the time of the representations, that [certain business programs] would be disastrous for the company but continued to tout their benefits publicly." 565 F.3d at 254. Plaintiffs allege no comparable facts in this case.

Partners CDO Fund v. Washington, 368 F.3d 228, 237 (3d Cir. 2004) ("[M]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud.") (citation omitted).

This is particularly true in the biotechnology context.[7] As the Fourth Circuit has explained, "[i]f we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the PSLRA." *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008). In *Cozzarelli*, Inspire's development stage drug for eye disease had achieved results of corneal clearing in Phase 3 trials. *Id.* at 621. The FDA required an additional trial, and the drug failed. *Id*. at 622. The plaintiffs alleged that defendants knew achieving corneal clearing was "nearly impossible" and misled investors as to the likelihood of success of the trial by characterizing it as "confirmatory" because the company needed to raise capital. *Id.* at 622, 627. The Fourth Circuit held that such allegations are insufficient to infer scienter, explaining:

> Based on the fact that defendants achieved corneal clearing in [earlier Phase 3 trials] and then set out to achieve it again in [the last trial], it is much more likely that defendants thought that [the last trial] would succeed than that they thought it would fail. Further proving the point, much of the complaint portrays [the drug] as the "lead development product" on which Inspire's future as a company depended. It is improbable that Inspire would stake its existence on a drug and a clinical trial that the company thought

[7] *E.g.*, *In re Vertex Pharms. Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 351, 354 (D. Mass. 2005) (rejecting as basis for strong inference of scienter biopharmaceutical company's "strong financial incentive" to produce positive reports about its leading candidate drug and to keep negative information about drug out of media for as long as possible, even though success with drug allowed company to complete merger with another pharmaceutical company and would have helped to make company's collaborative agreements with other pharmaceutical companies profitable); *In re Discovery Labs Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *14 (E.D. Pa. Nov. 1, 2006) (attached as Ex. 16) (rejecting as basis for strong inference of scienter biopharmaceutical company's need to keep stock price high in order to close equity financing agreements because "[t]his surely is the quintessential motive 'generally possessed by most corporate directors and officers'" and "does not show scienter") (citation omitted).

> was doomed to failure. Plaintiffs' inference of fraud based on the supposed impossibility of corneal clearing is thus not even plausible, much less convincing.

Id. at 627 (citation omitted). Likewise, here, the only plausible inference is that Repros believed that lower doses of Proellex would prove viable and that the interim data was supportive of that position. In fact, unlike Inspire, Repros never characterized the continued testing of Proellex as merely "confirmatory." Instead, Repros repeatedly told its investors that it had not yet completed pivotal and final trials on Proellex and that the final data might be negative. *See supra* at 3-5 and note 3.

Even if allegations about Repros's financing needs were sufficient to support a strong inference of scienter, Plaintiffs have failed to plead any specific supporting facts. For example, no facts are pleaded to suggest that Repros's capital requirements or financing needs when the Class Period began were any different than its prior needs. Repros had been experiencing significant operating losses since its inception and had been reporting publicly for more than a year that its ability to continue as a going concern depended on the success of the Proellex trials. (*See* Compl. ¶¶ 32-35); *see also supra* at note 5. Although Plaintiffs suggest that the September 30, 2009 financing deadline in the NIH Amendment was the impetus for the fraud, that deadline *did not even exist* at the beginning of the Class Period. (*See* Compl. ¶ 1 (marking July 1, 2009 as beginning of class period); ¶ 33 (stating that sixth amendment to Repros-NIH licensing agreement, which created September 30, 2009 financing deadline, was executed on July 7, 2009).) Therefore, it does not support an inference that Defendants engaged in any scheme with intent to defraud investors.

Plaintiffs' theory also lacks any logical basis. This is not the prototypical fraud-to-obtain-financing case, in which a plaintiff alleges that the defendant knew of an issue that would affect the company negatively, failed to disclose the issue, raised capital, and only then

made a full disclosure. *Cf., e.g.*, *Heller v. Goldin Restructuring Fund, L.P.*, 590 F. Supp. 2d 603, 622 (S.D.N.Y. 2008). For example, in *Heller*, the plaintiff alleged that the defendants knew that their fund was undercapitalized but withheld such information and, instead, affirmatively stated to potential investors that a prominent businessman had committed $40 million to the fund. *Id.* After the plaintiff was contractually committed to contribute capital, the defendants disclosed that the fund was, in fact, undercapitalized. *Id.* The *Heller* court held that such facts are consistent with a strong inference of scienter. *Id.*

Plaintiffs have alleged no comparable facts here. Plaintiffs have not pleaded any facts to show that the timing of the disclosures about the liver enzymes issue was in any way driven by the need to raise capital. Instead, Plaintiffs have alleged that Defendants hid *some* information about the liver enzymes issue starting July 1 in order to raise capital but then disclosed *all* information one month later, *despite having raised no capital at all*. The only logical inference, and certainly the more persuasive one, is that Defendants disclosed the information as soon as it was available to them, regardless of the company's capital needs.

C. Plaintiffs' Section 20(a) and control person liability claims must be dismissed.

Plaintiffs' secondary liability claims under Section 20(a) fail because the primary Section 10(b) claims must be dismissed for the reasons explained above. *See Shaw*, 537 F.3d at 545.

IV. CONCLUSION

For these reasons, Defendants respectfully request that the Court dismiss Plaintiffs' amended Consolidated Complaint, with prejudice, for failure to state a claim.

Respectfully submitted,

/s/ David D. Sterling
David D. Sterling
Fed. I.D. No. 07079
Texas Bar No. 00788730
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002
Telephone: 713.229.1459
Facsimile: 713.229.7759

ATTORNEY-IN-CHARGE FOR DEFENDANTS

OF COUNSEL:

Samuel Cooper
Fed. I.D. No. 19954
Texas Bar No. 00792427
Tracy N. LeRoy
Fed. I.D. No. 860752
Texas Bar No. 24062847
Amy Pharr Hefley
Texas Bar No. 24046046
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002
Telephone: 713.229.1234
Facsimile: 713.229.1522

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served electronically on all counsel of record on this 15th day of March, 2010.

/s/ David D. Sterling
David D. Sterling